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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,774	10/22/2003	Scott H. Gillis	14072-035001 / W 616	1593

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EXAMINER	
PAK, JOHN D	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,774	GILLIS ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,10 and 12-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,10 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-2, 4, 10 and 12-14 are pending in this application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4, 10 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Upon further review and reconsideration, it has been determined that it is unclear what is being claimed in the above noted claims. The independent claim 1 starts out "A nanocrystalline material" and ends with "wherein ... the nanocrystalline material is contained in an article in the form of a pill, a capsule, lozenge or a suppository."

It is unclear whether the claims are directed to the nanocrystalline material per se[1] or the nanocrystalline material that is formed as an article in the form of a pill, etc. Since the claim starts out as claiming the nanocrystalline material, it is unclear whether the article language is merely intended use language.

Put another way, it is unclear whether the claims are directed to a composition of matter category of invention (compound or mixture of compounds) or article of manufacture category of invention (pill, capsule, lozenge, suppository). Both categories cannot be claimed in one claim. Instant claim 4 is evidence that the independent claim

[1] Claims 1, 2, 10, 12, 13, 14 could read on the compound per se or an alloy per se. Claim 4 could read on a mixture of the compound per se with a pharmaceutically acceptable carrier. It does not appear that

and other dependent claims are readable on the nanocrystalline compounds per se (i.e. composition of matter) – presence of claim 4 is an indication that no other carrier or excipient may be readable on claim 1, which conveys a scope of the compounds/materials per se, i.e. composition of matter category of invention. The claims are rejected for lack of clarity.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 10, 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Burrell et al. (US 5,837,275, hereinafter Burrell '275).

Burrell '275 discloses nanocrystalline materials of one or more metals, including silver, gold, platinum and palladium, wherein the nanocrystalline material contains an element such as oxygen. See claims 1, 4, 7. Silver oxide is disclosed, which necessarily meets 1 wt% but not more than 90 wt% of oxygen (claim 7). Clusters of antimicrobial metals is disclosed (claim 2), wherein clusters are defined as small groups of atoms, ions or the like (column 4, lines 38-39). The nanocrystalline material can be

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any of the claims must necessarily be in the form of a pill, capsule, lozenge or suppository due to the way the claims are written.

coated onto an inert biocompatible carrier such as talc or cornstarch (column 13, lines 1-5).

The claims are anticipated to the extent that they read on the nanocrystalline materials per se. As explained earlier in this Office action, the language in claim 1, "wherein ... the nanocrystalline material is contained in an article in the form of a pill, a capsule, a lozenge or a suppository" is not clear in requiring the claimed invention to be in the form of such an article. The language can be interpreted as intended use language for a composition of matter.

The nanocrystalline materials possess at least antimicrobial activity (see claim 1 in Burrell '275), so applicant's feature of claim 12 is met. Talc or cornstarch meets the feature of claim 4. The at least two different metal elements feature of applicant's claim 14 is met by the "one or more anti-microbial metals" language of claim 1 of Burrell '275. The claims are thereby anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4, 10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell '275 in view of Spector (US 6,224,779).

Burrell '275 discloses nanocrystalline materials of one or more metals, including silver, gold, platinum and palladium, wherein the nanocrystalline material contains an element such as oxygen. See claims 1, 4, 7. Burrell et al. define the term "metal" or "metals" to include pure metals as well as oxides, nitrides, borides, sulfides, halides and hydrides (column 4, lines 27-30), all of which necessarily meet 1 wt% but not more than 90 wt% of the non-metal element component feature in applicant's claims. Clusters of antimicrobial metals is disclosed (claim 2), wherein clusters are defined as small groups of atoms, ions or the like (column 4, lines 38-39). The nanocrystalline material can be coated onto an inert biocompatible carrier such as talc or cornstarch (column 13, lines 1-5). Coatings on sutures or burn dressings, and incorporation into creams, polymers and other matrices are taught (column 6, lines 36-49). Burrell's Example 10 discloses nanocrystalline silver powder sprinkled onto adhesive tape. A pellet of nanocrystalline silver powder is also disclosed (column 19, lines 16-19). Improved antimicrobial effect due to "atomic disorder" is disclosed (see e.g., column 3, lines 57-65; column 19, lines 1-4 and 41-53).

Spector teaches packaging silver salts for disinfecting use in the form of pills, pellets or tablets (column 3, lines 34-41). The advantage of such packaging is to permit handling of chemicals without contact (column 3, lines 27-30). Spector establishes the well-known history of silver usage in the field of water disinfection (column 1, lines 36-57). Spector establishes the undesirability of silver precipitation (column 1, lines 27-35).

Burrell '275 does not expressly disclose a nanocrystalline material comprising Ag, Au, Pt and/or Pd and O, N, C, B, S, P, Si, halogen and/or H in an article form of "pill," capsule, lozenge or suppository. However, what Burrell '275 does teach is that such nanocrystalline materials (e.g. in powder form) possess improved antimicrobial properties due to their characteristic of providing sustained release of antimicrobial metal species (column 3, line 62 to column 4, line 7), which sustained release is "at an enhanced rate relative to its normal ordered crystalline state" (column 4, lines 53-54). The "enhanced solubility has broad applications" (emphasis added) (column 3, lines 66-67). Uses as antimicrobial powders, coatings on medical devices and burn dressings, and incorporation into creams, polymers, ceramics, paints (column 6, lines 36-49), clothing, footwear, diapers, tables, enclosures and wall coverings (column 9, lines 1-14) are disclosed. Formation into pellets is also disclosed (column 19, lines 16-19).

Therefore, even though an article form of pill, capsule, lozenge or suppository is not expressly disclosed by Burrell '275, such form would have been fairly suggested by the "broad applications" for which Burrell's improved antimicrobial metal compounds have been taught, taken with the uses and forms of silver compounds already known and practiced in the art. Spector would have provided sufficient motivation for one having ordinary skill in the art to formulate the improved nanocrystalline materials of Burrell '275 (same as claimed herein) as pills or pellets. The motivation arises from (i) the expected advantage of improved control of microorganisms from Burrell's improved

nanocrystalline materials, and (ii) the advantage of safe and convenient handling due to the pill or pellet form. From the broad applications of silver nanocrystaline materials taught by Burrell '275, taken with the well known use of silver compounds for disinfection purposes, utilization of Burrell's silver nanocrystalline materials as the silver salts would have been fairly suggested, particularly since the enhanced solubility of Burrell's nanocrystalline materials (column 3, line 67) would have addressed the undesirable silver precipitation problem noted by Spector.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Claims 1-2, 4, 10, 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell '275 in view of Fey (US 4,980,172).

Burrell '275 has been discussed above, and the discussion there is incorporated herein by reference. Further, it is noted that Burrell '275 discloses broad application of nanocrystalline metals such as silver and "any metal, metal alloy, or metal compound ... from which sustained release of metal species into solution is desired" (emphasis added) (column 4, lines 3-7).

Fey teaches an anti-smoking preparation, which provides a uniform concentration of silver ions in the mouth for smoking deterrence (column 2, lines 26-35). The lozenge form is preferred because it will "uniformly bathe the mouth with silver ions at low concentrations" (column 2, lines 66-68).

Burrell '275 does not expressly disclose a nanocrystalline material comprising silver and O, N, C, B, S, P, Si, halogen and/or H in an article form of a lozenge. However, what Burrell '275 does teach is that such nanocrystalline materials provide sustained release of the metal species (column 3, line 62 to column 4, line 7), which sustained release is "at an enhanced rate relative to its normal ordered crystalline state" (column 4, lines 53-54). The "enhanced solubility has broad applications" (emphasis added) (column 3, lines 66-67). Uses as antimicrobial powders, coatings on medical devices and burn dressings, and incorporation into creams, polymers, ceramics, paints (column 6, lines 36-49), clothing, footwear, diapers, tables, enclosures and wall coverings (column 9, lines 1-14) are disclosed.

Therefore, even though an article form such as lozenge is not expressly disclosed by Burrell '275, such form would have been fairly suggested by the "broad applications" for which Burrell's improved nanocrystalline metal compounds have been taught, taken with the uses and forms of silver compounds already known and practiced in the art. Fey would have provided sufficient motivation for one having ordinary skill in the art to formulate the improved nanocrystalline materials of Burrell '275 (same as

claimed herein) as a lozenge. The motivation arises from the expected advantage of sustained release of silver by using Burrell's improved nanocrystalline materials. The lozenge form is preferred precisely because it uniformly bathes the mouth with silver ions at low concentrations. One having ordinary skill in the art would have been motivated to select Burrell's nanocrystalline silver compounds to use in Fey's lozenges with the expectation that Burrell's sustained release at an "enhanced rate" would additionally provide the uniform bathing of the mouth with silver ions at low concentrations.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Claims 1-2, 4, 10, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell '275 in view of HCAPLUS abstract 1995:331180.

Burrell '275 has been discussed above, and the discussion there is incorporated herein by reference. Further, it is noted again that Burrell '275 discloses broad application of nanocrystalline metals such as silver and "any metal, metal alloy, or metal compound ... from which sustained release of metal species into solution is desired" (emphasis added) (column 4, lines 3-7).

HCAPLUS abstract 1995:331180 discloses a capsule that contains gold chloride and silver acetate for pharmaceutical treatment use.

Burrell '275 does not expressly disclose a nanocrystalline material comprising silver and O, N, C, B, S, P, Si, halogen and/or H in an article form of a capsule. However, what Burrell '275 does teach is that such nanocrystalline materials provide sustained release of the metal species (column 3, line 62 to column 4, line 7), which sustained release is "at an enhanced rate relative to its normal ordered crystalline state" (column 4, lines 53-54). The "enhanced solubility has broad applications" (emphasis added) (column 3, lines 66-67). Uses as antimicrobial powders, coatings on medical devices and burn dressings, and incorporation into creams, polymers, ceramics, paints (column 6, lines 36-49), clothing, footwear, diapers, tables, enclosures and wall coverings (column 9, lines 1-14) are disclosed.

Therefore, even though an article form such as a capsule is not expressly disclosed by Burrell '275, such form would have been fairly suggested by the "broad applications" for which Burrell's improved nanocrystalline metal compounds have been taught, taken with the uses and forms of silver compounds already known and practiced in the art. The HCAPLUS abstract would have provided sufficient motivation for one having ordinary skill in the art to formulate the improved nanocrystalline materials of Burrell '275 (same as claimed herein) as a capsule. The motivation arises from the expected advantage of sustained release of silver by using Burrell's improved

nanocrystalline materials. One having ordinary skill in the art would have been motivated to select Burrell's nanocrystalline silver and gold compounds to use in the capsule disclosed in the cited HCAPLUS abstract with the expectation that Burrell's sustained release at an "enhanced rate" would additionally provide the advantage of enhanced solubility and/or release.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Grounds of rejection which are not repeated herein from the previous Office action are hereby withdrawn in view of applicant's claim amendments and remarks.

It is noted for the record that during the prosecution of numerous applications related to this application, crystalline or nanocrystalline material composition inventions have been restricted as being distinct from methods of use thereof. Had there been claims in this application directed to a method invention, those claims would surely have been likewise restricted. Therefore, the Examiner will not make any obviousness type double patenting grounds of rejection herein over other pending applications which may claim methods of use of a pill, capsule, lozenge or suppository. If applicant is aware of

any applications in which pending and/or elected claims are directed to a composition of nanocrystalline materials in the form of a pill, capsule, lozenge or suppository, applicant is requested to inform the Examiner of the same.

Applicant is further requested to update all application data to reflect any abandoned or patented status of referenced U.S. patent applications, see e.g. specification pages 1-2, page 84 at lines 11-14.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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